Complete Summary

GUIDELINE TITLE

SAGES guidelines for office endoscopic services.

BIBLIOGRAPHIC SOURCE(S)

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). SAGES guidelines for office endoscopic services. Los Angeles (CA): Society of American Gastrointestinal and Endoscopic Surgeons (SAGES); 2008. 7 p. [7 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Society of American Gastrointestinal Endoscopic Surgeons (SAGES). Guidelines for office endoscopic services. Los Angeles (CA): Society of American Gastrointestinal Endoscopic Surgeons (SAGES); 2004 Mar. 6 p. [7 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Gastrointestinal disorders

GUIDELINE CATEGORY

Diagnosis
Screening

CLINICAL SPECIALTY

Anesthesiology
Gastroenterology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To ensure that patients having endoscopy in an office setting have the appropriate level of safety and quality

TARGET POPULATION

Patients with gastrointestinal symptoms and patients being screened for gastrointestinal cancer

INTERVENTIONS AND PRACTICES CONSIDERED

Office endoscopic services, including:

- Endoscopic privileges
- Prudent patient selection for procedure
- Proper patient instruction prior to procedure
- Safe conduction of conscious sedation
- Availability of emergency transport as needed
- Availability of equipment required to perform endoscopy
- Sufficient recovery of patients from procedure and sedation
- Preventive maintenance and testing of endoscopy equipment
- Implementation of protocols for personnel and patient protection from infectious disease
- Maintenance of patient records
- Documentation of informed consent for the procedure

MAJOR OUTCOMES CONSIDERED

- Complications of sedation
    - Respiratory failure
    - Cardiac arrest
- Complications of endoscopy
    - Bleeding
    - Perforation
    - Infection

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The data bases searched included

1. Cochrane Database of evidence based reviews
2. OVID Medline

Time frame was from 1996 to November 2008

The authors included all articles and had no criteria for exclusion due to the limited number of articles on the subject

Search Terms included

- Endoscopy guidelines
- Endoscopy
- Office based
- Office based endoscopy
- Office based Procedures

NUMBER OF SOURCE DOCUMENTS

22

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Level I	Evidence from properly conducted randomized, controlled trials
Level II	Evidence from controlled trials without randomization Or Cohort of case-control studies Or Multiple time series, dramatic uncontrolled experiments
Level III	Descriptive case series, opinions of expert panels

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Articles were divided and reviewed by a working group of four authors according to the protocol developed by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Guidelines Committee, and were graded for level of evidence by the authors. Levels of evidence (and subsequent recommendations) were approved by the SAGES Guidelines Committee and the SAGES Board of Governors.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This statement was reviewed and approved by the Board of Governors of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), November 2008.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Introduction

A number of factors including reimbursement have produced a demand for endoscopy to be performed in an office based setting as compared to a hospital or ambulatory center setting. Many gastrointestinal endoscopy procedures can be performed safely in the office setting. To ensure that patients having endoscopy in an office setting have the appropriate level of safety and quality, standards of

care need to be set and met. These standards should be similar if not the same as the standards set for an institutional setting.

Privileges

Only adequately trained and experienced endoscopists should perform endoscopy in an office setting. These endoscopists must meet accepted standards of training and experience. He or she should have staff privileges to perform the same procedure in an institutional setting or qualify for such privileges based on established guidelines such as described by the Society of American Gastrointestinal Endoscopic Surgeons (SAGES) Guidelines for Granting of Privileges for Gastrointestinal Endoscopy.

Physical Environment

Facilities should have been constructed in accordance with local and regional building codes, and those recommended by applicable accreditations organizations, and should be certified as an Ambulatory Surgery Center, or be capable of accreditation. Patient changing areas should be made available away from common areas and a secure location for storing belongings and appropriate bathroom facilities must also be available. The facility should comply with the standards of the Americans with Disabilities Act. A waiting room should be available for family members. Appropriate consultation and treatment rooms must be constructed to assure patient privacy. Mechanisms for the safe evacuation of conscious and sedated patients must exist.

Endoscopy suites should be adequate with regard to size, and should provide the following as a minimum: 1) Reduced illumination from ambient light, 2) Sized for passage of a rolling stretcher through all doorways and passages, 3) Unrestricted access to both sides, and head and foot of the patient, 4) Unimpeded view of monitoring equipment, 5) Sufficient storage for supplies, 6) Appropriate ventilation, 7) Sound and sight privacy boundaries, and 8) Mechanisms for summoning emergency personnel that can be activated without leaving the patient.

Patient Selection

Prudent selection of both procedures and patients appropriate for office endoscopy is critical. Procedures having intrinsic risk or requiring technology not available in the endoscopist's office should be performed in an institutional setting.

All patients scheduled for endoscopic procedures should be assigned an anesthesia risk score, using the American Society of Anesthesiologists (ASA) score. Patients with an ASA score of IV should not undergo endoscopy in the office setting. Patients with an ASA score of III should be further assessed for appropriateness of the office setting. ASA III patients may be acceptable candidates if deemed so by a physician qualified to assess the specific disability and its impact on anesthesia and procedure risks. All women of child-bearing age should be queried about the possibility of being pregnant. Pregnancy testing may be considered in women of child bearing age unless there is a history of total hysterectomy, bilateral tubal ligation or absent menses for one year (menopause).

Patient Safety

Patients should receive clear pre procedure instructions. Confirmation of important compliance issues such as nothing by mouth (NPO) status should be documented. Any modifications to standing medication schedules should be provided at the time of scheduling.

Administration of Conscious Sedation

Conscious sedation used as an adjunct to endoscopic procedures must be administered safely. Intravenous access should be established prior to administering sedatives, and maintained until the patient has recovered sufficiently to permit safe discharge. There must be appropriate monitoring and expertise in managing potential associated complications such as respiratory depression and cardiac arrest. Baseline pulse, respiratory rate, oxygen saturation, and blood pressure should be recorded before administration of any sedatives. Pulse oximetry, cardiac monitoring, automated blood pressure recording, and supplemental oxygen should be routinely employed. Emergency medications and equipment used for cardiopulmonary resuscitation, including adequate oral suction, a defibrillator, ambu bag, laryngoscope, and emergency airway tray must be readily available and checked on a daily basis.

Anesthesia should be administered only by a licensed, qualified and competent practitioner. Registered professional nurses (RNs) who administer analgesic or sedative drugs as part of a medical procedure (including but not limited to *Certified Registered Nurse Anesthetists (CRNAs)* must have training and experience appropriate to the level of anesthesia administered and function in accordance with their scope of practice. Registered professional nurses (RNs) must have documented competence to administer conscious sedation and to assist in any support or resuscitation measures as required. The individual administering conscious sedation and/or monitoring the patient cannot be involved in uninterruptible duties. Supervision of the sedation/analgesia component of the medical procedure should be provided by a *physician who is physically present*, who is qualified by *law, regulation, or hospital appointment to perform* and supervise the administration of the sedation/analgesia or minor conduction blockade and who has accepted responsibility for supervision. The *physician* providing supervision should:

i. Assure that an appropriate preanesthetic examination and evaluation is performed proximate to the procedure
ii. Prescribe the anesthesia
iii. Assure that qualified practitioners participate
iv. Remain physically present during the entire perioperative period and immediately available for diagnosis, treatment, and management of anesthesia-related complications or emergencies
v. Assure the provision of indicated post-anesthesia care

A registered nurse who is certified in Basic Cardiac Life Support (BCLS) should monitor the patient postoperatively and have the capability of administering medications as required for analgesia, nausea/vomiting, or other indications. Monitoring in the recovery area should include pulse oximetry and non-invasive blood pressure measurement. The patient should be assessed periodically for level

of consciousness, pain relief, or any untoward complication. A protocol must be present defining the method and means of transfer to a higher level of care institution in the event a complication or unforeseen issue develops with the patient during the procedure or in the post-procedure period.

All office endoscopy patients must be sufficiently recovered from procedures and sedation prior to discharge, and should meet uniform standard discharge criteria. Patients who receive sedation must have their vital signs, respiratory status, and mentation monitored in a manner consistent with that utilized for patients treated in the hospital setting. If sedation has been used, the patient must be accompanied by a responsible adult at discharge, and be transported home and prohibited from driving or engaging in even low risk activities for a standardized period of time dictated by the sedative agents utilized. Written instructions regarding common complications, directions for returning for emergency evaluation and caution as to continued functional impairment for many hours following conscious sedation are appropriate and should be provided to all patients.

Training of Staff

See the original guideline document for full details.

Equipment and Medication Requirements

See the original guideline document for full details.

Documentation

Each patient should have at minimum a current brief history and physical examination, reviewed by the endoscopist immediately prior to the procedure. Serious cardiopulmonary or other disease should be excluded by appropriate clinical and, if necessary, laboratory evaluation.

The patient chart should contain the clinical examination and evaluation, a list of medication allergies and current medications, the justification for the procedure, the description of the endoscopy and pathology found, and the patient's status on discharge. Informed consent for the procedure should be documented in the chart consistent with local professional standards and applicable state law.

Records should be maintained so that complications and problems can be identified and compliance with recommendations for clinical and endoscopic care ensured. Records and clinical documents should adhere to the same standards required for institutions by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and other regulatory agencies, and should conform to Health Insurance Portability and Accountability Act (HIPAA) standards and those others in effect.

There should be an appropriate mechanism of relating findings and the results of pathologic studies to patients and referring physicians, as well as for the tracking of specimens. Indications, findings, treatment results, and complications should be kept in a database, and periodic peer review of this data should be performed.

Written policy and procedure manuals should be maintained and kept up to date, and a written agreement with a Clinical Laboratory Improvement Act (CLIA)-certified pathology lab should be maintained for the processing of specimens.

Quality Improvement

Appropriate records should be kept of accepted indicators that reflect quality levels such as: 1) Cancellation of booked procedures, 2) Unplanned admission to the operating room, 3) Unplanned overnight admission, and 4) Delay in patient discharge.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate standards of practice for gastrointestinal endoscopy performed in the office setting

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Guidelines for clinical practice are intended to indicate preferable approaches to medical problems as established by experts in the field. These recommendations will be based on existing data or a consensus of expert opinion when little or no data are available. Guidelines are applicable to all physicians who address the clinical problem(s) without regard to specialty training or interests, and are intended to indicate the preferable, but not necessarily the only acceptable approaches. Guidelines are intended to be flexible. Given the wide range of specifics in any health care problem, the surgeon must always choose the course best suited to the individual patient and the variables in existence at the moment of decision.
- Guidelines are developed under the auspices of the Society of American Gastrointestinal Endoscopic Surgeons and its various committees, and

approved by the Board of Governors. Each clinical practice guideline has been systematically researched, reviewed and revised by the guidelines committee, and reviewed by an appropriate multidisciplinary team. The recommendations are therefore considered valid at the time of its production based on the data available. Each guideline is scheduled for periodic review to allow incorporation of pertinent new developments in medical research knowledge, and practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness
Staying Healthy

IOM DOMAIN

Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). SAGES guidelines for office endoscopic services. Los Angeles (CA): Society of American Gastrointestinal and Endoscopic Surgeons (SAGES); 2008. 7 p. [7 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1996 (revised 2008 Nov)

GUIDELINE DEVELOPER(S)

Society of American Gastrointestinal and Endoscopic Surgeons - Medical Specialty Society

SOURCE(S) OF FUNDING

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

GUIDELINE COMMITTEE

SAGES Guidelines Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Steven Heneghan, MD; Jonathan Myers, MD; Robert Fanelli, MD, *Chair*; David Earle, MD; Jeffrey Hazey, MD; John Kilkenny, III, MD; Jay Redan, MD; Raymond Price, MD; Keith Apelgren, MD; Ronald Clements, MD; Timothy Farrell, MD; Erika Fellinger, MD; Stephen Haggerty, MD; James Korndorffer, MD; Thom Lobe, MD; Sumeet Mittal, MD; David Overby, MD; Patrick Reardon, MD; William Reed, MD; David Renton, MD; E. Matthew Ritter, MD; Alan Saber, MD; J. Salameh, MD; Dimitrios Stefanidis, MD; William Richardson, MD, *Co-Chair*

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Members of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) disclose potential conflicts of interest and pertinent financial relationships prior to serving as faculty for SAGES-sponsored educational events, delivering presentations at scientific meetings, etc. Additionally, members of SAGES Committees disclose their potential conflicts of interest and pertinent financial relationships annually as a condition of committee membership.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Society of American Gastrointestinal Endoscopic Surgeons (SAGES). Guidelines for office endoscopic services. Los Angeles (CA): Society of American Gastrointestinal Endoscopic Surgeons (SAGES); 2004 Mar. 6 p. [7 references]

GUIDELINE AVAILABILITY

Electronic copies: Available from the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Web site.

Print copies: Available from the Society of American Gastrointestinal Endoscopic Surgeons (SAGES), 11300 W. Olympic Blvd., Suite 600, Los Angeles, CA 90064; Web site: www.sages.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on November 19, 1999. The information was verified by the guideline developer on February 15, 2000. This NGC summary was updated by ECRI Institute on May 3, 2007. The updated information was verified by the guideline developer on May 13, 2007. This NGC summary was updated by ECRI Institute on June 5, 2009. The updated information was verified by the guideline developer on July 14, 2009.

COPYRIGHT STATEMENT

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx .

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

Date Modified: 8/3/2009


DEPARTMENT OF HEALTH & HUMAN SERVICES • USA